

**LDR Spine Cervical Interbody Fusion System (ROI-C and MC+ devices)****510(k) Summary of Safety and Effectiveness**

JUL 14 2009

<b>SUBMITTED BY</b>	LDR Spine USA 4030 W. Braker Lane, Suite 360 Austin, TX 78759
<b>FOREIGN ESTABLISHMENT REGISTRATION NUMBER</b>	3004788213
<b>US AGENT ESTABLISHMENT REGISTRATION NUMBER</b>	3004903783
<b>CONTACT PERSON</b>	Noah Bartsch Manager, Clinical, Regulatory and Quality Affairs Phone: 512-344-3319 Fax: 512-344-3350
<b>SUBMISSION PREPARED BY</b>	Lisa Peterson QA Consulting, Inc. Phone: 512-507-0746
<b>DATE PREPARED</b>	July 13, 2009
<b>CLASSIFICATION NAME</b>	ODP 888.3080 - Intervertebral Fusion Device with Bone Graft, Cervical
<b>COMMON NAME</b>	Intervertebral Body Fusion Device (ODP) Spinal Vertebral Body Replacement Device (MQP)
<b>PROPRIETARY NAME</b>	LDR Spine Cervical Interbody Fusion System
<b>PREDICATE DEVICE(S)</b>	Predicate devices include several recently down classified cages, as well as cleared VBR systems: - BAK/C (P980048, Zimmer Spine, Approved 4/20/01) - Affinity Cage System (P000028, Medtronic, Approved 6/13/02) - ROI-C VBR (K083857, LDR Spine, Cleared 2/12/09) - MC+ Partial VBR (K043479, LDR Spine, Cleared 6/30/05)

## **SUBSTANTIAL EQUIVALENCE**

The LDR Spine Cervical Interbody Fusion System was determined to be substantially equivalent to several commercially available systems.

## **DEVICE DESCRIPTION**

### ROI-C

ROI-C consists of 'D' shaped blocks in a variety of heights and length x width configurations, and features an enclosed graft space. Lateral rows of teeth are present on both the caudal and cephalic surfaces of the device. The flat of the 'D' shape represents the anterior most portion of the device, and includes features for attachment to instrumentation for insertion, and the slots for the anchors.

The D-shaped ROI-C PEEK implants (PEEK OPTIMA LT1) feature two slots which allow for use with specially designed (and optional) supplemental fixation – the ROI-C Anchoring Plate. The Anchoring Plate, made of titanium alloy (TiAl6V4) can be inserted to obtain fixation to the vertebral bone, by locking in place to the PEEK implant via Locking Tabs.

### MC+

MC+ consists of 'D' shaped blocks in a variety of heights and length x width configurations, and features an open or enclosed graft space design. Lateral rows of teeth are present on both the caudal and cephalic surfaces of the device. The flat of the 'D' shape represents the anterior most portion of the device, and includes features for attachment to instrumentation for insertion, and the slots for the Anchoring Clip.

MC+ is intended to be used with supplemental internal fixation (i.e. anchoring clips). MC+ is designed for use with one Anchor Clip. The mechanism by which the Anchoring Clip locks into the MC+ device is achieved via the the mating slot in the anterior face and the anti-backout tabs of the Anchoring Clip itself.

## **INDICATIONS:**

When used as an intervertebral body fusion device, the LDR Spine Cervical Interbody Fusion System (ROI-C and MC+ devices) is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2–T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The LDR Spine Cervical Interbody Fusion System implants are to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental internal fixation is required to properly utilize this system.

When used as a vertebral body replacement device, the ROI-C and MC+ implants are indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system. These devices are intended to be used with autograft or allograft bone.

**MECHANICAL TEST DATA**

Mechanical test results demonstrate that the proposed LDR Spine Cervical Interbody Fusion System is substantially equivalent to the predicate device. Testing was performed in accordance with ASTM F2077 and ASTM F2267.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 14 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

LDR Spine USA  
% Mr. Noah Bartsch, M.S., R.A.C.  
Manager, Clinical, Regulatory & Quality Affairs  
4030 W. Braker Lane, Suite 360  
Austin, TX 78759

Re: K091088

Trade/Device Name: LDR Spine Cervical Interbody Fusion System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: ODP, MQP  
Dated: April 12, 2009  
Received: April 15, 2009

Dear Mr. Bartsch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson

Director

Division of Surgical, Orthopedic  
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K091088

Device Name: **LDR Spine Cervical Interbody Fusion System**

### Indications for Use:

When used as an intervertebral body fusion device, the LDR Spine Cervical Interbody Fusion System (ROI-C and MC+ devices) is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The LDR Spine Cervical Interbody Fusion System implants are to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental internal fixation is required to properly utilize this system.

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use         
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

                     (EXT for MXM)  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K091088